

"Spherisator" ["Spheristor"]). The Spherisator [Spheristor] can produce microspheres of alumina at high temperature (2,000+ F), but can also "encapsulate" material at lower temperatures (400 to 500 degrees F. FIG. 12 shows a method of producing microspheres using a machine such as the Spherisator [Spheristor]. A molten solution of alumina ( $Al_2O_3$ ) is forced by pressure through channels 142 in a nozzle 144. The molten alumina exits the nozzle as a fine spray of droplets 146 of alumina, which when cooled become spherical due to the surface tension of the droplet. By proper controlling the cooling and collection of the droplets, microspheres 100 are formed and collected in bin 150.

A similar method can be used to produce the macrospheres as shown in FIG. 13. A mix of a selected microsphere is blended with polyethylene pellets, and flows through the machine, subjected to heat, which liquefies the polyethylene making the solution 160. Pressure forces the solution 160 through the channels 142 in the nozzle 144. Droplets so formed then are in a free fall, and take on the spherical form due to surface tension. Droplets 162 exiting the nozzle contain microspheres in a solution of polyethylene. Cold air then solidifies the spheres. As the drops cool the microsphere coalesce together in a sphere and are bound by the polyethylene, forming macrospheres. The polyethylene also coats the surface of the macrosphere and surface tension results in the macrospheres being spherical with a smooth surface. The formed macrospheres 110 are collected in bin 150.

Another method for forming macrospheres is micro injection molding. Standard methods of preparation of the materials for this composite would be used, with a blend of the selected alumina microspheres and polyethylene. The mold would be bi-valved in form, consisting of two hemispheres. Due to the small size of the macrospheres, a die could have about 10,000 cavities, in an area of about one square foot, and produce that

number of macrospheres with each cycle of the machine. The usual branching "tree" (inflow conduit for the composite), would permit easy removal, and the macrospheres would be extracted by mechanical means, such as fracturing and screening. Tumbling and polishing would remove any "flash" from the spheres.

The use of high density polyethylene was selected for the macrospheres as it serves several specific functions. First, it provides rigid and strong bonding of the microspheres; second, it converts the otherwise "bumpy" outer / surface layer of the microspheres to a smooth surface; third, it is soft enough to permit the needle point to enter the triangular capture area between adjacent microspheres; and fourth, it has the non-stick property required for the formation of the glove. The last property relates to the contact of the macrospheres with an elastomer used in forming a surgical glove by injection molding, which is further explained below in reference to FIG. 18. The choice of Nylon or Teflon could provide similar properties, in varying degrees.

An alternate method of forming macrosphere is to sinter or fuse the microspheres in the Spherisator [Spheristor], to form the Macrosphere, was considered. However, this was found not to be desirable, since fusing the microspheres produces significant deformation of the spherical shape of the microspheres, which compromises the capture function of the macrosphere. This method could be effective however with much larger microspheres.

Another type of macrosphere is a porous macrosphere, which is not formed of microspheres. This macrosphere design differs structurally from the macrosphere having microspheres, but retains the capture property to a similar, but somewhat less effective, degree. This type of macrosphere is more easily made by a machine such as the Spherisator [Spheristor], and can be made in larger sizes than the type of macrospheres with

microspheres. A porous macrosphere can be made to be more than 60 mils in diameter. FIG. 14 shows a porous macrosphere 170 having many pores 172. The porous macrosphere 170 is coated with polyethylene 174, as shown in FIG. 15 to give the finished porous macrosphere 176 a smooth spherical surface. A sharp instrument or needle 178 is captured when the polyethylene yields to the needle point on contact. Lateral translation, skidding, or "skiving" is prevented as the needle point contacts the porous surface in a random pore, which stops the motion of the needle, and further stabilizes it from lateral translation.

FIG. 16 shows a method of producing microspheres using a machine such as the Spherisator [Spheristor]. A molten solution 180 of aluminum oxide ( $Al_2O_3$ ) and a second material which volatilizes at a lower temperature than the alumina is forced by pressure through channels 142 in nozzle 144. When the droplets 182 containing the aluminum oxide and the second material exit the nozzle, then while the aluminum oxide cools, the second material, which is no longer at pressure, volatilizes creating in the process pores of 5 to 20 mils on the surface of the macrospheres 170 collected in bin 150. In a finishing step, the large porous macrospheres are tumbled with an abrasive to better open up the surface, and remove any intact surface film of alumina.

Then in a second pass through the Spherisator [Spheristor], a coating of polyethylene, about 10 mil thick is applied at a lower temperature, about 400 to 500 degrees F. This gives the porous macrosphere 176 its final form, with a smooth, spherical surface. This process is illustrated in FIG. 17 showing the porous macrospheres and liquefied polyethylene 184 being forced at pressure through the channels 142 in the nozzle 144. As the droplets 186 fall they take on a spherical form due to surface tension. The formed and coated porous macrospheres 176 are collected in bin 150.

Now the fabrication of a glove from the macrospheres is described with reference to FIGs. 18-25.

The foregoing replacement paragraphs are shown again below in clean form:

The first method utilizes existing technology, as used by the company "Brace GmbH", which uses a machine (called a "Spherisator"). The Spherisator can produce microspheres of alumina at high temperature (2,000+ F), but can also "encapsulate" material at lower temperatures (400 to 500 degrees F. FIG. 12 shows a method of producing microspheres using a machine such as the Spherisator. A molten solution of alumina ( $\text{Al}_2\text{O}_3$ ) is forced by pressure through channels 142 in a nozzle 144. The molten alumina exits the nozzle as a fine spray of droplets 146 of alumina, which when cooled become spherical due to the surface tension of the droplet. By proper controlling the cooling and collection of the droplets, microspheres 100 are formed and collected in bin 150.

A similar method can be used to produce the macrospheres as shown in FIG. 13. A mix of a selected microsphere is blended with polyethylene pellets, and flows through the machine, subjected to heat, which liquefies the polyethylene making the solution 160. Pressure forces the solution 160 through the channels 142 in the nozzle 144. Droplets so formed then are in a free fall, and take on the spherical form due to surface tension. Droplets 162 exiting the nozzle contain microspheres in a solution of polyethylene. Cold air then solidifies the spheres. As the drops cool the microsphere coalesce together in a sphere and are bound by the polyethylene, forming macrospheres. The polyethylene also coats the surface of the macrosphere and surface tension results in the macrospheres being spherical with a smooth surface. The formed macrospheres 110 are collected in bin 150.

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Then in a second pass through the Spherisator, a coating of polyethylene, about 10 mil thick is applied at a lower temperature, about 400 to 500 degrees F. This gives the porous macrosphere 176 its final form, with a smooth, spherical surface. This process is illustrated in FIG. 17 showing the

porous macrospheres and liquefied polyethylene 184 being forced at pressure through the channels 142 in the nozzle 144. As the droplets 186 fall they take on a spherical form due to surface tension. The formed and coated porous macrospheres 176 are collected in bin 150.

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